

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:

“Track One Cases”

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**MALLINCKRODT’S REPLY MEMORANDUM IN SUPPORT OF
ITS MOTION FOR PARTIAL SUMMARY JUDGMENT**

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INTRODUCTION

Mallinckrodt's Motion for Partial Summary Judgment (the "Motion") identifies three discrete issues on which the record demonstrates no dispute of material fact. In opposition, Plaintiffs filed a 27-page brief—over three times as long as Mallinckrodt's opening brief—chock-full of irrelevant evidence, unsupported speculations, and bald and conclusory assertions designed to distract the Court from the actual issues presented by the Motion. Indeed, despite pages and pages of purported "evidence," nowhere in Plaintiffs' opposition (or the record) will the Court find the following: (1) any evidence that Mallinckrodt promoted its generic opioid products to physicians; (2) any evidence that Mallinckrodt shipped any suspicious orders to Cuyahoga or Summit County (the "Bellwether Counties"); or (3) any evidence that Mallinckrodt's suspicious order monitoring program was deficient after 2012.

Until this point, Plaintiffs have not been forced to identify any actual evidence on the basis of which a jury could hold Mallinckrodt liable for the sweeping claims made in their Third Amended Complaint. But after more than a year of discovery, millions of pages of produced documents, and hundreds of depositions, the time has finally come for Plaintiffs to show their hand as to each individual defendant and each individual claim. Indeed, it is black-letter law that once the moving party makes an initial "'showing' . . . that there is an absence of evidence to support the nonmoving party's case," the burden shifts to the Plaintiff to "designate '*specific facts*' showing that there is a genuine issue for trial.'" *Celotex Corp. v. Catrett ex rel. Estate of Catrett*, 477 U.S. 317, 324-25 (1986) (emphasis added); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986) (explaining that the non-moving party must set forth "significant probative evidence" showing a genuine dispute of material facts); *Peterson v. Johnson*, 714 F.3d 905, 910 (6th Cir. 2013). If Plaintiffs "fail[] to make the necessary showing on an element upon which [they] would bear the burden of proof at trial, [defendants are] entitled to summary judgment." *Peterson*, 714 F.3d at

910. The Court must therefore isolate and dispose of Plaintiffs' claims to the extent they are supported by mere "speculation and hunches," *Hartsel v. Keys*, 87 F.3d 795, 802 (6th Cir. 1996), the repetition of "vague and conclusory allegations," *Emmons v. McLaughlin*, 874 F.2d 351, 358 (6th Cir. 1989), statements containing "rumors, conclusory allegations and subjective beliefs," *Mitchell v. Toledo Hosp.*, 964 F.2d 577, 584–85 (6th Cir. 1992), or "threadbare assertion[s]" of a material dispute, *K.V.G. Properties, Inc. v. Westfield Ins.*, 900 F.3d 818, 822 (6th Cir. 2018). Plaintiffs' opposition falls well short of meeting their burden, and accordingly, this Court must grant summary judgment for Mallinckrodt to dispose of the factually unsupported claims identified in Mallinckrodt's Motion.

ARGUMENT

I. Plaintiffs fail to identify any evidence that Mallinckrodt falsely promoted its generic opioid medications to physicians.

Mallinckrodt's opening brief requests partial summary judgment on Plaintiffs' marketing claims related to its generic opioid products because Plaintiffs have not shown that Mallinckrodt falsely promoted its generics products to physicians. MNK Mem. Supp. Mot. Par. Summ. J. at 3 (Dkt. 1898-2/1907-2). This argument can come as no surprise to Plaintiffs. In his Report and Recommendation on the Manufacturer Defendants' motion to dismiss, Magistrate Judge Ruiz wrote, as to Plaintiffs' alleged marketing scheme: "Defendants will certainly have the opportunity to request the identity of these doctors during discovery, and Plaintiffs will need to support their theories with evidence to withstand a motion for summary judgment or persuade the trier of fact." Rep. & Recommendation 25 n.20 (Dkt. 1025) ("R&R"). Despite countless requests from Mallinckrodt, Plaintiffs and their witnesses have not identified a single prescriber in the Bellwether Counties that was exposed to allegedly "deceptive messages" by Mallinckrodt about its generic

opioid products. Plaintiffs' failure in this regard should be recognized and summary judgment entered.

A. Plaintiffs acknowledge that Mallinckrodt did not promote its generic opioid products to physicians.

Plaintiffs' opposition is not only devoid of any evidence of Mallinckrodt's false promotion of its generics opioid products to physicians; it identifies *no* evidence at all of any promotion of Mallinckrodt's generic opioid products to physicians, false or otherwise. Plaintiffs concede as much at various points in their brief. *See, e.g.*, Pl. Mem. Opp. MNK Mot. Partial Summ. J. at 10 (Dkt. 2271/2293) (writing that certain materials purportedly provided to patients and physicians were "not specific to any Mallinckrodt product, generic or branded," and that related materials were "not promoting any specific branded or generic product"); *id.* at 11-12 (twice conceding that certain "fundamental misrepresentations" that are "central to [their] allegations in this case" are "not specific to a particular branded or generic product" and "not specific to a particular product").

Instead, Plaintiffs resort to two examples of Mallinckrodt's alleged promotion of its *branded* opioids, apparently to bolster their opposition, despite the fact that Mallinckrodt's motion concerns only Mallinckrodt's marketing (or demonstrated lack thereof) of its generic opioid products. *Id.* at 10-11. As to Mallinckrodt's alleged distribution of unbranded promotional materials at trade shows, Plaintiffs have presented no evidence that these materials were ever given to any doctor, let alone that they led any doctor to prescribe Mallinckrodt's generic opioid products or any opioid products at all for that matter. In short, the record simply offers no evidence that Mallinckrodt promoted its generic products to physicians at all, much less in a misleading or false manner.

B. Plaintiffs' opposition reflects an attempt to distract the Court and evade the legal hurdles they must clear to survive summary judgment.

Rather than answering Mallinckrodt's argument that it did not promote its generic opioid medications to physicians with evidence (because they cannot), Plaintiffs instead pack their brief with more than eight pages of irrelevant allegations. Plaintiffs attempt to shift the focus away from the lack of evidence supporting their claim of misleading generic promotion to trade shows, pharmacists, and Mallinckrodt's addiction treatment business.

With respect to Mallinckrodt's attendance at trade shows, while this evidence might reflect exposure to groups "who often make product *purchasing* decisions" (Pl. Mem. Opp. at 7), it says nothing about the relevant inquiry: marketing to those who make *prescribing* decisions. As stated in its opening brief, Mallinckrodt sells generic opioid medications to wholesalers, distributors, and retail pharmacies, and competes for market share in those spaces. MNK Mem. Supp. Mot. Par. Summ. J. at 3-4. Plaintiffs cannot plausibly cite Mallinckrodt's attendance at trade shows as evidence of its promoting its generic products to physicians, or of efforts to grow the market for its products. A prescription necessarily exists before a pharmacist can fill it. What's more, Plaintiffs' insinuation that pharmacists influenced physicians' prescribing decision is unsupported by any record evidence.

Similarly, that Mallinckrodt maintains an addiction treatment business is not evidence that Mallinckrodt promoted its generic opioid products to doctors. Accordingly, the Court should disregard this discussion as totally irrelevant and enter summary judgment in Mallinckrodt's favor.

C. Plaintiffs fail to point to any evidence that Mallinckrodt's alleged statements were false or misleading.

To the extent Mallinckrodt distributed unbranded marketing materials to pharmacists at trade shows (something that could not form the basis for Plaintiffs' generics false marketing claim, as just explained), Plaintiffs provide no evidentiary support at all for their assertions that

Mallinckrodt's materials contained "multiple misleading statements," "numerous misrepresentations," or "misleading information" Pl. Mem. Opp. at 9-10. Plaintiffs simply list a handful of statements in their opposition and baldly assert that they are "misleading," "false," and "misrepresentations," without providing any support for those assertions. *See, e.g., id.* at 5 ("With older adults, start dose low, go slow, but go!"); *id.* at 9 ("It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy.").

At this stage of the proceeding, these statements are not rendered false or misleading simply by Plaintiffs' say-so, or by their reference to Mallinckrodt's awareness of the risk of opioid addiction. And, in fact, Plaintiffs' opposition ignores record evidence affirmatively demonstrating that certain of these statements are indeed *true*. The FDA, for example, has stated that addiction rarely occurs from the use of opioid medications. Davison Decl. Ex. 1 FDA Guide to Safe Use of Pain Medicine ("According to the National Institutes of Health, studies have shown that properly managed medical use of opioid analgesic compounds (taken exactly as prescribed) is safe, can manage pain effectively, and *rarely causes addiction.*") (emphasis added).

After more than one year of litigation, extensive discovery, and millions of pages of produced documents, because Plaintiffs have presented no evidence that any physician was misled by Mallinckrodt to prescribe a Mallinckrodt generic opioid, summary judgment should enter in Mallinckrodt's favor on Plaintiffs' generics false marketing claims.

II. Plaintiffs still have failed to identify a single suspicious order shipped to Cuyahoga or Summit County.

Plaintiffs' opposition is notable in that it still fails to identify a single suspicious order that Mallinckrodt shipped to any customer in the Bellwether Counties. Without any such evidence, Plaintiffs' diversion claims—which are based on a purported failure by Mallinckrodt to halt and

report suspicious orders—must fail. Plaintiffs’ attempt to manufacture a disputed issue of material fact on this point is directly contradicted by Plaintiffs’ own experts. Rafalski Dep. Tr. at 635:2-13 (Dkt. 1969-19/1983-16). Although Plaintiffs point first to their putative expert, Lacey Keller, even she fails to identify a single suspicious order that Mallinckrodt shipped to any customer in a Bellwether County.¹ Ms. Keller did not identify a suspicious order, and could not even identify which of Mallinckrodt’s flagged orders were shipped or unshipped. Keller Dep. Tr. at 361:24-362:21 (Dkt. 1963-13/1979-6) (“They appear in the peculiar order data for Mallinckrodt Whether or not those were actually shipped or unshipped, I couldn’t answer as to whether, whether that happened.”). None of Plaintiffs’ other experts was able to identify a suspicious order either. *See e.g.*, McCann Rep. at 4-6 (Dkt. 2000-14/1999-13); McCann Dep. Tr. at 311:20-313:6 (Dkt. 1966-17/1981-12); Whitelaw Dep. Tr. at 836:4-12 (Dkt. 1972-7/1985-19).

A. Plaintiffs’ discussion of Mallinckrodt’s market share and chargeback data does not create a genuine dispute of material fact.

Rather than identify any actual suspicious order, Plaintiffs emphasize Mallinckrodt’s market share. But, the amount of opioids Mallinckrodt produces is a quantity that is regulated and approved by the DEA pursuant to the aggregate production quota. Pl. Mem. Opp. at 13; Harper-Avilla Dep. Tr. at 34:2-35:24; 44:7-47:3; 90:14-93:25 (Dkt. 1962-20/1977-24). Aggregate volume is by default not suspicious, because DEA approves the quantity “necessary to be

¹ As Defendants point out in their Memorandum in Support of Defendants’ Motion to Exclude Lacey Keller’s Opinions and Proposed Testimony (Dkt. 1917-1/1914-1), despite Keller’s purported attempt to “trace” Mallinckrodt’s orders to shipments that distributors made to the Counties, Keller Rep. at 9 (Dkt. 2000-7/1999-7), Plaintiffs now concede that such an exercise is not possible. Pl. Mem. Opp. at 14. Nevertheless, Plaintiffs seek to salvage Keller’s opinion by claiming that rather than tracing Mallinckrodt’s orders, Keller merely means to “estimate” what portion of certain orders distributors “wound up” shipping to pharmacies in the Counties. *Id.* at 12-13. Even that watered-down opinion must be excluded under *Daubert*, because, among other things, Plaintiffs fail to support Keller’s assumption that, any shipment a distributor made within 30 days of receiving a shipment that Mallinckrodt at one point flagged as “peculiar,” necessarily consisted of pills from that shipment, rather than some other order not flagged as peculiar. *Id.* at 13.

manufactured . . . to provide for the estimated medical, scientific, research and industrial needs of the United States. . . .” 21 C.F.R. § 1303.11(a).

Plaintiffs also assert that Mallinckrodt should have used chargeback data to identify allegedly problematic downstream transactions and physicians. Pl. Mem. Opp. at 14-15. As an initial matter, as explained more fully in Manufacturer Defendants’ Opposition to Plaintiffs’ Motion For Partial Summary Adjudication That Defendants Did Not Comply With Their Duties Under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them, (Dkt. 2180/2181) (“Defendants’ Opposition to Plaintiffs’ CSA Compliance Brief”), while Mallinckrodt had no legal duty to use chargeback (or any other data for that matter) to monitor downstream transactions, it did so anyway. What’s more, chargeback data does not enable a manufacturer to do what Plaintiffs contend Mallinckrodt should have done: that is, to stop dishonest doctors from writing bad scripts. Chargeback data does not even show which doctors wrote a prescription and, in any event, manufacturers receive chargeback data only long after a downstream transaction has already occurred. Buthusiem Rep. at 5-6 (Dkt. 1939-5/1936-5).²

B. Plaintiffs’ discussion of diversion in Florida does not create a genuine dispute of material fact.

Plaintiffs also point to Mallinckrodt’s alleged awareness of diversion of opioids shipped to Florida. Pl. Mem. Opp. at 17. That Mallinckrodt became aware of possible diversion in Florida is at best evidence of Mallinckrodt’s diligence, not evidence that Mallinckrodt ever shipped a suspicious order to the Bellwether Counties. Without supporting evidence, Plaintiffs’ unsupported (by admissible evidence) insinuations that opioids from Florida *may* have been diverted to Ohio

² Similarly, Plaintiffs’ sensationalized mention of “Aunt Sandra” cannot change the undisputed facts that the order referenced in that email was shipped as a part of a DEA-reported shipment to a DEA-registered distributor, in a non-Bellwether County, presumably pursuant to a validly written prescription. It most certainly does not connect any Mallinckrodt conduct to any harm allegedly suffered in the Bellwether Counties.

cannot save Plaintiffs' diversion claims from summary judgment.

C. Plaintiffs' discussion of Mallinckrodt's Memorandum of Agreement with DEA does not create a genuine dispute of material fact.

As Mallinckrodt explained in its opposition to Plaintiffs' CSA Compliance Brief, the Administrative Memorandum of Agreement between Mallinckrodt and the DEA ("MOA") contains two limited admissions, neither of which precludes summary judgment here: (1) **prior to 2012**, "certain aspects" of Mallinckrodt's suspicious order monitoring ("SOM") program did not meet the standards outlined in DEA *guidance letters*; and (2) it did not meet certain recordkeeping and physical security requirements at its factory in upstate New York that were *unrelated* to suspicious order monitoring. Defs.' Opp. Pls.' CSA Compliance Br. at 21. As to the first admission, DEA's guidance letters are not legally binding and do not impose obligations under the CSA or otherwise. *See Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 452 F.3d 798, 808 (D.C. Cir. 2006) (National Highway Traffic Safety Administration letters with "policy guidelines" "are nothing more than general policy statements with no legal force. They do not determine any rights or obligations, nor do they have any legal consequences."). And the second admission is unrelated to Plaintiffs' allegations.

III. Plaintiffs fail to provide any evidence that Mallinckrodt's SOM program was inadequate after 2012.

Plaintiffs' final attempt to salvage their diversion claim and avoid summary judgment is to argue that Mallinckrodt's SOM program was inadequate. But, Plaintiffs' arguments fail for two totally independent, but related, reasons. First, Mallinckrodt moves for summary judgment only as to the post-2012 period. Accordingly, none of the voluminous pre-2012 evidence that Plaintiffs cite in their opposition is relevant at all. Second, Plaintiffs' experts concede as to the post-2012 period that *they cannot say Mallinckrodt's post-2012 system was deficient*. This is not a surprise, given that the other purported "evidence" Plaintiffs cobble together in their opposition is not

sufficient to raise a genuine issue of disputed material fact as to the post-2012 time period on which Mallinckrodt moves.

A. Plaintiffs' discussion of pre-2012 allegations is irrelevant.

Plaintiffs devote much of their opposition to discussing *pre*-2012 matters. This is entirely unresponsive to Mallinckrodt's opening brief, which explicitly moved for summary judgment on its SOM program *after* 2012. *See* MNK Mem. Supp. Mot. Par. Summ. J. at 6–8 (Dkt. 1898-2/1907-2). As Defendants' Opposition to Plaintiffs' CSA Compliance Brief explains in greater detail, there was nothing deficient about Mallinckrodt's pre-2012 anti-diversion program. *See* Defs.' Opp. Pls.' CSA Compliance Br. 13-21. Mallinckrodt's SOM program had both algorithmic and non-algorithmic components. Mallinckrodt screened all new customers, monitored incoming orders, met regularly with its customers and raised red-flag concerns about diversion as appropriate, reviewed every DEA 222 form to verify a valid DEA registration, conducted audits and media searches, and more. But, given the state of the record, Mallinckrodt chose not to move as to the pre-2012 period, instead limiting itself to the post-2012 period—as to which Plaintiffs' own experts concede that they cannot identify any deficiencies in Mallinckrodt's program and as to which there is clearly not evidence in the record to create a material dispute of fact on this issue.

B. There is no evidence that Mallinckrodt's anti-diversion efforts since 2012 were inadequate.

1. Plaintiffs' own purported experts concede there is no evidence of post-2012 deficiencies.

Plaintiffs retained two witnesses to opine on the alleged insufficiency of defendants' controlled substances compliance programs: (1) James Rafalski, a former DEA investigator; and

(2) Seth Whitelaw, a food and drug attorney.³ Both of these putative experts expressly declined to state that Mallinckrodt's anti-diversion efforts after 2012 were inadequate.

Mr. Rafalski's discussion of Mallinckrodt in his report was focused on pre-2012 systems. Rafalski Rep. at 162-67 (Dkt. 2000-22/1999-21). And at his deposition, Mr. Rafalski explicitly stated *he offered no opinion on Mallinckrodt's anti-diversion program after 2011*. Rafalski Dep. Tr. at 665:19–666:8 (“Q. Okay. So fair to say in this litigation, you’re not providing any opinion with respect to Mallinckrodt’s suspicious order monitoring program after 2011? . . . A . . . so that would be an accurate statement as of today.”) Yet, Plaintiffs conveniently *gloss over Mr. Rafalski altogether*—they do not even mention his name in their opposition brief. Understandably so.

Plaintiffs instead focus their opposition on Attorney Whitelaw, who similarly stated that he could not offer an opinion as to Mallinckrodt's anti-diversion program after 2012. Whitelaw Dep. Tr. at 938:9-13 (Dkt. 1972-7/1985-19) (“Q. Are you stating today that you cannot offer an opinion as to the adequacy of Mallinckrodt’s anti-diversion program post 2012? A. That is what I’m saying.”). Plaintiffs then appear to try to blame Attorney Whitelaw’s admission on Mallinckrodt by saying this is somehow a consequence of Mallinckrodt’s document production and stating that Mallinckrodt’s document production was “heavily weighted towards pre-2012 documents.” Pl. Mem. Opp. at 26. This inaccurate assertion is yet another transparent attempt to distract the Court from Plaintiffs’ lack of evidence. As a matter of sheer numbers, Mallinckrodt produced more documents from the *post*-2012 time period than the pre-2012 time period—and Plaintiffs have known this for some time because, months ago, they emailed Mallinckrodt a chart listing Mallinckrodt’s document production by year. Davison Decl. Ex. 2 (email from Plaintiffs

³ Both of these witnesses’ opinions are currently the subject of *Daubert* motions. See Defendants’ *Daubert* Motion to Exclude the Opinions Offered by James Rafalski (Dkt. 1884/1900); Defendants’ *Daubert* Motion to Exclude the Opinions of Seth B. Whitelaw (Dkt. 1881/1918).

to J. Pantina). It was *Plaintiffs* (not Mallinckrodt) who decided how many post-2012 documents to give Attorney Whitelaw to review, and tellingly, *they decided to give him only nine*, perhaps because the remainder supported Mallinckrodt’s case, not Plaintiffs’. Pl. Mem. Opp. Ex. 105. Plaintiffs cannot now credibly say that the reason Attorney Whitelaw does not have an opinion about Mallinckrodt’s SOM program since 2012 is because he didn’t have enough documents to review. Plaintiffs have had Mallinckrodt’s discovery materials all along and chose not to give Attorney Whitelaw sufficient documents from which to conclude that Mallinckrodt’s post-2012 program was deficient—because it was not.

2. The limited post-2012 allegations Plaintiffs cite are not sufficient evidence to create a disputed issue of material fact.

Without any evidence of a post-2012 deficiency (as their experts’ admissions demonstrate), Plaintiffs resort to their own say-so in their opposition. According to Plaintiffs, isolated orders, they (not their experts) say, demonstrate Mallinckrodt conducted only “minimal and perfunctory” “due diligence.” Pl. Mem. Opp. at 21. As explained elsewhere, Mallinckrodt did not, as a matter of law, have any “duty” under the Controlled Substances Act (“CSA”) to conduct any due diligence even on any orders flagged as suspicious.⁴ But regardless, Plaintiffs present no evidence (beyond their saying so) that any of the orders they note were actually suspicious, shipped, or diverted, or that the diligence Mallinckrodt conducted was not adequate. Without such evidence, Plaintiffs’ purported “evidence” amounts to nothing more than mere speculation—not sufficient to survive summary judgment. At summary judgment Plaintiffs can no longer rely on bald and conclusory

⁴ See Defendants’ Opposition to Track One Plaintiffs’ Motion for Partial Summary Judgment for Partial Summary Adjudication of Defendants’ Duties Under the Controlled Substances Act at 7-13 (Dkt. 2159); Distributors’ Opposition to Plaintiffs’ Motion for Partial Summary Adjudication that Defendants Did Not Comply With Their Duties Under the Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them at 1-19 (Dkt. 2149); Manufacturer Defendants’ Opposition to Plaintiffs’ Motion for Partial Summary Adjudication on Defendants’ Compliance With the Controlled Substances Act at 1-12 (Dkt. 2180/2181) (all three briefs incorporated here by reference).

allegations, but are required to present actual, admissible evidence to support their claims. *See Peterson*, 714 F.3d at 910; *Wiley v. United States*, 20 F.3d 222, 226 (6th Cir. 1994). They have plainly failed to do so here.

Plaintiffs’ assertion that Mallinckrodt “reported to the DEA and stopped shipment on only 143 orders out of 26,000 suspicious orders (and over 35 million total orders),” *see* Pl. Mem. Opp. at 22–23, is both wrong⁵ and irrelevant. After 2012, it is undisputed that Mallinckrodt ***held and reported to the DEA every order its system flagged as unusual***. *See, e.g.*, Dkt. 2180-13/2181-13 (Mallinckrodt 2012 SOM Policy at Bates begin MNK-T1_0007476261); Dkt. 2180-14/2181-14 (Mallinckrodt 2015 SOM Policy at Bates begin MNK-T1_0000511246); Dkt. 2180-21/2181-21 (May 6, 2013 AM SOM Report at Bates begin MNK-T1_0002216027); Dkt. 2180-22/2181-22 (May 6, 2013 PM SOM Report at Bates begin MNK-T1_0002217298); Dkt. 2180-23/2181-23 (May 7, 2013 AM SOM Report at Bates begin MNK-T1_0002217300); Dkt. 2180-24/2181-24 (May 7, 2013 PM SOM Report at Bates begin MNK-T1_0007708172). Mallinckrodt reviewed each of these orders and ultimately released only those that it determined were not suspicious after a diligence review. *Id.* What’s more, Plaintiffs provide no basis for their insinuation that the number (or percentage) of orders Mallinckrodt actually stopped was too low or problematic. Plaintiffs do not present any *evidence* that the post-2012 orders Mallinckrodt shipped were suspicious, nor do they provide any *evidence* in support of their apparent belief that some (larger)

⁵ The 35 million orders figure is simply wrong—that is the number *chargebacks*, not orders, that Mallinckrodt received between 2012 and 2016. During that period, Mallinckrodt shipped 406,872 orders of opioid products. MNK-T1_0007897646. Nat’l Direct Sales Data (slipsheet for MNK-T10007897646, which Mallinckrodt will submit in native format) (Dkt. 1898-5/1907-5). Moreover, those orders were shipped to large distributors, who then filled individual orders at pharmacies. The chargeback data reflects a request from the distributor for a reconciliation between what the distributor sold the product to the pharmacy for and what the distributor paid for it. Buthusiem Rep. at 3-4 (Dkt. 1939-5/1936-5). Therefore, the number of chargebacks is much higher than the number of orders Mallinckrodt actually shipped to distributors.

percentage of orders should have been stopped. In short, Plaintiffs have introduced nothing that defeats summary judgment on this point.

Plaintiffs' three-page discussion of two non-parties to this litigation is yet another distraction. As an initial matter, the indictments and charges against Miami Luken and Rochester Drug Company are hearsay and are thus inadmissible. *See Gritton v. Disponett*, No. 3:05-cv-75-JMH, 2007 WL 3407459, at *10 (E.D. Ky. Nov. 14, 2007) ("Absent a conviction, it follows that these indictments do not come within the scope of Rule 803(22) and remain inadmissible hearsay"). And "it is well settled that only admissible evidence may be considered by the trial court in ruling on a motion for summary judgment." *Fultz & Son, Inc. v. Browning-Ferris Indus. of Ohio, Inc.*, No. 3:1-cv-53, 2019 WL 3068277, at *3 (N.D. Ohio July 12, 2019) (quoting *Wiley*, 20 F.3d at 226; *Beyene v. Coleman Sec. Servs., Inc.*, 854 F.2d 1179, 1181 (9th Cir. 1988)). Regardless, Mallinckrodt had no visibility into the orders shipped by these companies, nor (obviously) was Mallinckrodt aware of the charges against these companies prior to the charges being filed. To the extent that Plaintiffs suggest that Mallinckrodt should not have sent certain orders to these distributors, Plaintiffs provide no evidence that any of the orders Mallinckrodt shipped to them were suspicious. And Plaintiffs' discussion of downstream pharmacies ignores that Mallinckrodt had no obligation to monitor such orders—yet it nevertheless did so using the tools it had available. *See* Manufacturer Defendants' Opposition to Plaintiffs' Motion for Partial Summary Adjudication on Defendants' Compliance With the Controlled Substances Act at 5-15, 19-20 (Dkt. 2180/2181).

In sum, Plaintiffs have offered no evidence that precludes the limited summary judgment that Mallinckrodt seeks. This Court should reject Plaintiffs' attempts to misconstrue the record to manufacture a disputed issue of material fact when none exists. This Court should grant

Mallinckrodt's motion for partial summary judgment on all diversion-based claims at least as to Plaintiffs' post-2012 allegations.

CONCLUSION

Summary judgment should enter for Mallinckrodt on Plaintiffs' marketing claims to the extent they are based on Mallinckrodt's generic opioid products and on Plaintiffs' diversion claims as to the time period after 2012.

Dated: August 16, 2019

Respectfully submitted,

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LOCAL RULE 7.1(f) CERTIFICATE OF SERVICE

This brief, which is under 13.5 pages, adheres to the limits set forth in the Court's Order Regarding Pretrial Motions for "Track One" Trial, ECF No. 1653 and subsequent agreement by the parties, approved by Special Master Cohen.

Dated: August 16, 2019

/s/ *Brien T. O'Connor*

Brien T. O'Connor

CERTIFICATE OF SERVICE

I, Brien T. O'Connor, hereby certify that the foregoing document was served via file transfer protocol and email to all counsel of record.

/s/ *Brien T. O'Connor*

Brien T. O'Connor

APPENDIX A

Deposition Transcripts	Date	Pltf/Def	Sealed Dkt No.	Public Dkt No.
Harper-Avilla, Stacy	04/11/19	Third Party	1962-20	1977-24
Keller, Lacey	06/13/19	Plaintiff	1963-13	1979-6
McCann, Craig	05/09/19	Plaintiff	1966-17	1981-12
Rafalski, James	05/14/19	Plaintiff	1969-19	1983-16
Whitelaw, Seth	05/17/19	Plaintiff	1972-7	1985-19

Expert Reports	Date	Pltf/Def	Sealed Dkt No.	Public Dkt No.
Buthusiem, Edward	05/10/19	Defendant	1939-5	1936-5
Buzzeo, Ronald	06/28/19	Defendant	1939-6	1936-6
Keller, Lacey	04/15/19	Plaintiff	2000-7	1999-7
McCann, Craig J.	03/25/19	Plaintiff	2000-14	1999-13
Rafalski, James	04/15/19	Plaintiff	2000-22	1999-21

Other Documents	Date*	Pltf/Def	Sealed Dkt No.	Public Dkt No.
Judge Ruiz Report and Recommendation	10/5/2018	Court	-	1025
Defendants' <i>Daubert</i> Motion to Exclude the Opinions of Seth B. Whitelaw	07/19/19	Defendant	1881	1918
Defendants' <i>Daubert</i> Motion to Exclude the Opinions Offered by James Rafalski	07/19/19	Defendant	1884	1900
Mallinckrodt's Memorandum in Support of its Motion for Partial Summary Judgment	07/19/19	Defendant	1898-2	1907-2
Memorandum in Support of Defendants' Motion to Exclude Lacey Keller's Opinions and Proposed Testimony	07/19/19	Defendant	1917-1	1914-1
Mallinckrodt National Direct Sales Data slipsheet, at Bates begin number MNK-T1_0007897646	07/19/19	Defendant	1898-5	1907-5
Distributors' Opposition to Plaintiffs' Motion for Partial Summary Adjudication that Defendants Did Not Comply With Their Duties Under the Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them	08/07/19	Defendant	2149	-

Other Documents	Date*	Pltf/Def	Sealed Dkt No.	Public Dkt No.
Defendants' Opposition to Track One Plaintiffs' Motion for Partial Summary Judgment for Partial Summary Adjudication of Defendants' Duties Under the Controlled Substances Act	08/09/19	Defendant	2159	-
Manufacturer Defendants' Opposition to Plaintiffs' Motion For Partial Summary Adjudication That Defendants Did Not Comply With Their Duties Under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them	08/12/19	Defendant	2180	2181
Mallinckrodt Suspicious Order Monitoring Procedure, dated October 18, 2012, at Bates begin number MNK-T1_0007476261	08/12/19	Defendant	2180-13	2181-13
Mallinckrodt Suspicious Order Monitoring Procedure, dated August 17, 2016, at Bates begin number MNK-T1_0000511246	08/12/19	Defendant	2180-14	2181-14
Mallinckrodt May 6, 2013 AM SOM Report at Bates begin MNK-T1_0002216027	08/13/19	Defendant	2180-21	2181-21

Other Documents	Date*	Pltf/Def	Sealed Dkt No.	Public Dkt No.
Mallinckrodt May 6, 2013 PM SOM Report at Bates begin MNK-T1_0002217298	08/14/19	Defendant	2180-22	2181-22
Mallinckrodt May 7, 2013 AM SOM Report at Bates begin MNK-T1_0002217300	08/15/19	Defendant	2180-23	2181-23
Mallinckrodt May 7, 2013 PM SOM Report at Bates begin MNK-T1_0007708172	08/16/19	Defendant	2180-24	2181-24
Plaintiffs' Memorandum in Opposition to Defendant Mallinckrodt's Motion for Partial Summary Judgment	8/13/2019	Plaintiff	2271	2293

* Date refers to date filing appeared on the docket